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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,137	12/19/2001	Lu-Yieng Liu	12674-005001	4889
26161 75	90 01/27/2005		EXAMINER	
FISH & RICHARDSON PC			SITTON, JEHANNE SOUAYA	
225 FRANKLII			ART UNIT PAPER NUMBER 1634	
BOSTON, MA	. 02110			

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
Advisory Action	10/025,137	LIU ET AL.				
,	Examiner	Art Unit				
	Jehanne S Sitton	1634				
The MAILING DATE of this communication appe	ars on the cover sheet with the c	orrespondence add	ress			
THE REPLY FILED 03 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.						
PERIOD FOR RE	PLY [check either a) or b)]					
a) The period for reply expires 4_months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension						
fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
1. A Notice of Appeal was filed on Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.						
2. The proposed amendment(s) will not be entered because:						
(a) ☑ they raise new issues that would require further consideration and/or search (see NOTE below);						
(b) ⊠ they raise the issue of new matter (see Note below);						
(c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or						
(d) they present additional claims without canceling a corresponding number of finally rejected claims.						
NOTE: see attachment.						
3. Applicant's reply has overcome the following rejection(s):						
4. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).						
5. The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because:						
6. The affidavit or exhibit will NOT be considered becaraised by the Examiner in the final rejection.	ause it is not directed SOLELY to	o issues which were	e newly			
7. For purposes of Appeal, the proposed amendment explanation of how the new or amended claims we			ınd an			
The status of the claim(s) is (or will be) as follows:						
Claim(s) allowed: <u>none</u> .						
Claim(s) objected to: <u>none</u> .						
Claim(s) rejected: <u>1-15,23-26 and 36-43</u> .						
Claim(s) withdrawn from consideration: <u>27-35</u> .						
8. The drawing correction filed on is a) approved or b) disapproved by the Examiner.						
9. Note the attached Information Disclosure Statement(s)( PTO-1449) Paper No(s)						
10. Other:						

Application/Control Number: 10/025,137 Page 2

Art Unit: 1634

## **ATTACHMENT**

- 1. The proposed amendment will not be entered for the following reasons. The proposed amendment to claims 8 and 13 raise the issue of new matter. The specification does not appear to provide support for hybridization in claim 8 delimited by positions corresponding to SEQ ID NO: 13. Further the specification does not provide support for hybridization delimited by positions corresponding to SEQ ID NO: 12. Further, the amendment to claims 8 and 36, also require further search and consideration under 35 USC 112/first paragraph, 35 USC 102 and 35 USC 103. The scope of the claims has been changed such the claims have been amended to change the limitation that a nucleic acid contain a sequence to the limitation that the nucleic acid hybridize to a specific SEQ ID NO. This represents a broadening and changes the scope of the claims.
- 2. The declaration under 37 CFR 1.132 has not been considered because it does not address issues that were raised solely in the final rejection. The declaration addresses issues that were raised in the first office action and could have been presented as evidence in response to the first office action. Accordingly, it is not timely and will not be considered. At cursory glance, applicant should note that the declaration states at part 3 "the two pairs of primers... were used to amplify the corresponding target gene from nucleic acid samples of ....It was found that ... the EC-23/EC-24 primer pair failed to amplify a predicted 863 bp product" which raises the question as to whether the bacteria in the sample tested contained the copy of the gene (as opposed to variants of the gene which contain polymorphisms) which was used to generate the

primers. The use of the term "corresponding" is confusing and makes it unclear as to which specific sequence these bacteria contained.

- 3. With regard to the response's traversal of the rejections, any arguments directed to the proposed amended claims will not be considered as they are not drawn to the instantly pending claims.
- 4. With regard to the traversal of the rejection made under 35 USC 112/first paragraph, it should be noted that the response asserts that the claims mirror example 9 of the Written Description guidelines. This assertion is confusing because neither the instantly pending claims nor the proposed claim amendments recite both encoding language and hybridization language. Additionally, none of the claims are drawn to "encoding". Additionally, instant claim 8 is drawn to a nucleic acid produced by amplification, which does not mirror example 9.
- 5. With regard to the traversal of the rejection made under 35 USC 103, such arguments have been thoroughly reviewed but were found unpersuasive. The response asserts that even if one skilled in the art would have combined the cited references, he or she would have to choose the recited primers from an astronomical number of candidates. This argument as well as MPEP 2144.08 (cited in the response) have been thoroughly reviewed. This argument is not found convincing. The office action specifically addressed why one of ordinary skill in the art would be motivated to target a specific portion of the E. coli genome (see office action page 13), because it was conserved. The primers or probes that the ordinary artisan would be motivated to construct also represents a subgenus of the possible sequences that could be constructed based on

Application/Control Number: 10/025,137 Page 4

Art Unit: 1634

a single accession number alone. However, these sequence references were applied in combination. Further, the examiner provided a thorough review of the state of the art and why one would be motivated to construct the subgenus that contains significant overlap with the genus of nucleic acid sequences encompassed by the claims. Additionally, the rejection addressed the fact that the specific sequences of SEQ ID NO: 1-8 were not obvious in view of the teachings of the closest prior art. Arguments with regard to the declaration submitted under 37 CFR 1.132 will not be considered for the reasons set forth above. Additionally, it should be noted that such arguments are unclear as the examiner did not make the assertion regarding "amplifying contemplated products". The previous office actions were directed to constructing nucleic acids using a known sequence to detect or amplify that known sequence, not a contemplated one.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are

Application/Control Number: 10/025,137

Art Unit: 1634

available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

Page 5

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Jehanne Sitton

Primary Examiner

Art Unit 1634

124/05